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| 09/469,717 | 12/21/1999 | HUGH L. NARCISO JR. | 353532000710 | 5304 |

7590 01/21/2004

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| EXAMINER |
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DROESCH, KRISTEN L

| ART UNIT | PAPER NUMBER |
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3762

DATE MAILED: 01/21/2004

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/469,717

Applicant(s)

NARCISO, HUGH L.

Examiner

Kristen L Droesch

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-60 and 63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-60 and 63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 December 1999 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 47-60, and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 60, applicants set forth “. . . the tubular member being transformable upon application of energy to the tubular member between a fluent state in which the tubular member is radially expandable . . . and a non-fluent state in which the tubular member retains the end portion of the graft lumen in its expanded state”. In other words, applicant is claiming a tube that is transformed from a viscous liquid, expanded and solidified upon the application of energy. This recitation describes a curable material since curable materials (thermoset materials) can be transformed from a liquid to a solid by cross-linking. Applicants have pointed out that they intended to claim the “deformable” embodiment disclosed in the specification as opposed to the “curable” embodiment disclosed on pages 14-15. Therefore, the above claim recitation is inaccurate. As set forth in the specification on page 5, lines 22-27, the deformable tubular member is transformed into its fluent state by the application of energy, it is expanded, and then returns to its non-fluent state following expansion *when the energy supply is discontinued*. This is contrary to the claim language setting forth that the tubular member is transformed from a fluent state to a non-fluent state upon the application of energy.

Regarding claims 47-48, it is unclear how the fluent material can be pre-shaped and have a bend, or extend at 30-45⁰ to a longitudinal centerline.

Art Unit: 3762

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 49-55, 58-60, and are rejected under 35 U.S.C. 102(e) as being anticipated by Slepian (5,634,946).

Regarding claim 60, Slepian shows a fastener comprising a tubular member made of a deformable material sized and dimensioned for receiving an end portion of a graft lumen, which is transformable upon application of energy between a non-fluent state and a fluent state in which the tubular member is radially expandable (Col. 10, lines 46-Col. 11, line 5, Col. 12, lines 9-12, and 37-45, Col. 13, lines 13-16).

With respect to claims 49-51, Slepian shows that the tubular member is formed of a biocompatible, bioerodable polymeric material (Col. 7, lines 32-44, Col. 8, lines 4-15).

Regarding claim 52, Slepian shows the polymer is either a homopolymer or a copolymer (Col. 7, lines 46-49).

With respect to claim 53, Slepian shows the polymeric material is polycaprolactone (Col. 8, lines 16-46).

Regarding claims 54-55, Slepian shows the tubular member has an adhesive surface (Col. 12, lines 9-12, Col. 12, lines 52-56, Col. 14, lines 40-46)

Art Unit: 3762

With respect to claims 58-59, Slepian shows the tubular member is impregnated with anti-platelet, anti-thrombus, anti-inflammatory, and anti-proliferative compounds (Col. 9, lines 25-43).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Nash et al (6,056,762). Slepian is as explained before. Slepian teaches that the initial pre-deployment design and size of the polymer sleeve will be dictated by the specific application based upon the final physical, psychological, and pharmacological properties desired (Col. 12, lines 28-32). Although Slepian does not teach that the tubular member is pre-shaped to have at least a first bend along the length of the member or a portion of the tubular member extends at an angle of between 30° and 90° relative to a longitudinal centerline, attention is directed to Nash et al. which shows an anastomosis system comprising a tubular member (22) with a first bend along the length of the member (Fig. 3). Nash et al. shows that a portion of the tubular member extends at an angle between 30° and 90° relative to a centerline (Fig. 3, Col. 6, lines 44-47). Nash et al. teaches that the angled configuration facilitates insertion into the target vessel (Col. 6, lines 46-50). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the tubular member of Slepian with a first bend or a portion of the

Art Unit: 3762

tubular member extending at an angle between 30° and 90° relative to a centerline as Nash et al. teaches in order to facilitate insertion into a target vessel.

7. Claims 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Pathak (5,662,712). Slepian is as explained before. Although Slepian does not teach of including in the tubular member a chromophore or dye, attention is directed to Pathak which teaches of forming polymeric materials that include a chromophore such as a dye or pigment (Col. 2, lines 54-59). Pathak teaches that the chromophore serves to absorb light produced by a light source and convert it to thermal energy that acts to heat the polymer. It would have been obvious to one with ordinary skill in the art at the time the invention was made to include in the tubular member of Slepian a chromophore in the form of a dye, as taught by Pathak in order for the tubular member to be transformable by the application of light energy.

8. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Slepian in view of Hubbell (5,410,016). Slepian is as explained before. Although Slepian does not teach that the material is selected from a group consisting of polyethylene-glycol (PEG) base hydrogels, acrylates, and acrylated urethanes, attention is directed to Hubbell which teaches tissue contacting materials formed from polyethylene-glycol (PEG) base hydrogels, acrylates, and acrylated urethanes (Col. 5, lines 15-23, and Col. 27, lines 53-55). Hubbell teaches that the acrylates permit rapid polymerization and gelation and can be polymerized by several initiating systems. Hubbell teaches that PEG is hydrophilic and water soluble and has excellent biocompatibility. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to use this group of materials for the device of Slepian since Hubbell teaches that this group of materials are rapidly transformable upon the application

Art Unit: 3762

of energy between a non-fluent state and a fluent state, are water soluble, and have excellent biocompatibility.

Response to Arguments

9. Applicant's arguments filed 11/24/03 have been fully considered but they are not persuasive.

10. In response to applicant's argument that Slepian does not describe or suggest a fastener comprising a tubular member formed of a deformable member, the examiner is unconvinced. Like applicants, Slepian shows both deformable tubular materials and curable materials. Therefore, it cannot be implied that Slepian does not show a deformable tubular fastener just because he also shows a curable material. Furthermore, the grounds of rejection applied above were already applied in several previous office actions, Paper Nos. 5, 10, and 13.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Art Unit: 3762

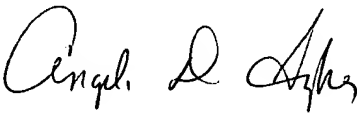
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185.

The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


kld



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